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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO
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DONALD L OTTO
RENNER OTTO BOISSELLE & SKLAR
1621 EUCLID AVENUE 19TH FLOOR
CLEVELAND OH 44115

EXAMINER	
EISENSCHENK, F	
ART UNIT	PAPER NUMBER
1816	9

DATE MAILED: 04/15/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/6/96

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-22 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).
☐ Interview Summary, PTO-
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES

15. Claims 1-22 are currently pending.

16. Claims 1, 5, 6, 7, and 20 have been amended.

17. Claim 22 is newly added.

18. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. The specification is objected and claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The specification does not define the anti-fibrotic agents. It appears from the specification that only those anti-fibrotic agents which inhibit the activity of a fibrotic agent will work in the claimed invention. Merely binding an agent with an antibody will have little effect if the antibody will not inhibit the agents activity. Applicant is invited to clarify this issue.

Applicant states that anti-fibrotic agents inhibit scarring or reduce fibrosis. Applicant has pointed to sections of the specification for support of these definitions. However, the specification refers only to those agents listed in claim 20 as having these attributes. Therefore applicant should limit the claimed invention to the agents listed in claim 20 as amended. Applicants' specification fails to provide a written description and enable any anti-fibrotic agent other than those disclosed within this specification. It is suggested that the claims be amended to recite "antibodies which neutralize TGF-β_1, TGF-β_2, PDGF".

20. The specification is objected and claims 1, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The claims are directed to a composition comprising an non-fibrotic growth factor [e.g. TGF-β_1] together with an anti-fibrotic agent [e.g. an antibody to TGF-β_1]. The specification fails to provide any direction for the use of such a composition e.g. the specification fails to provide the concentration of agents. Equimolar amounts of such agents will expectedly bind each other and thereby be rendered useless in such a composition for use in treating wounds.

Applicant does not appear to have traversed this rejection.

21. The specification is objected and claims 1, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and for failing to adequately teach how to make and/or use the invention, i.e. for failing to provide an enabling disclosure. The claims are directed to a composition comprising anti-sense oligonucleotides or

ribozymes. However, the specification is devoid of direction on how to use such a composition. There is no direction on how these particular agents are to be directed into the cell nucleus in vivo.

Applicant does not appear to have traversed this rejection.

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 1, 3, 7-11, 17, 18 and newly added claim 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Geistlich et al. [WO 90/03810 (1990)]. Please note a typographical error was made in this rejection claim 6 was inadvertently inserted for claim 7, the rejection does not change in substantively, and therefore a new grounds is not necessary here. Geistlich et al. teach delayed release compositions for wound healing. Such compounds are interspersed in a hydrogel. Geistlich et al. teach the preparation of the hydrogel composition. See abstract and pages 1-4. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Geistlich et al. is the same as that claimed. Thus, the Geistlich et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

Applicant states that "Geistlich et al. does not teach or suggest the use of the specific combinations of agents required by applicant's claims. Applicant states that "[n]o teaching in Geistlich et al. relates to non-fibrotic growth factors used alone or used in combination with fibrotic growth factors, and fibrotic growth factors together with anti-fibrotic agents" Applicant concludes that since "Geistlich et al. does not teach each element of" the claims the reference does not anticipate the claimed invention. This is not persuasive. Considering the instant invention -- Claim 1 is drawn to a composition for use in healing wounds comprising at least one non-fibrotic growth factor with or without fibrotic growth factors in a pharmaceutically acceptable carrier [Geistlich et al. teach this - the abstract clearly states a hydrogel containing one or more gellable proteins . . . containing one or more growth factors selected from epidermal growth factor, human fibroblast growth factor, human insulin-like growth factor and platelet derived growth factor for use in wound healing]. Claim 3 is drawn to FGF, as discussed immediately above Geistlich et al. teach fibroblast growth factor. Claim 17 adds that the carrier is a biopolymer -- Geistlich et al. address this see pages 3-6, and claim 2 of Geistlich et al. Claim 18 is drawn to a preparation of such a composition. Geistlich et al. address this see pages 3-6 of Geistlich et al. Claim 21 is drawn to at least one non-fibrotic growth factor being FGF with at least one fibrotic growth factor. Geistlich et

al. teach this see abstract. Claims 8-11 refer to the non-fibrotic factors/agents are present in the composition in an inactive form, by encapsulation, degradable by external stimulus, including in vivo enzymes or heat. Geistlich et al. teach this at pages 3-6. Application of the hydrogel to the body will inherently result in degradation by in vivo enzymes or heat.

Applicants' arguments have been considered and have not been found persuasive for the reasons of record. The claimed invention is of such a broad scope that the Geistlich reference reads on the claimed invention.

24. Claims 1, 2, 6, 12 and 14-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cerletti et al. [EP 0 433 225 (1990)]. Cerletti et al. teach a method for treating wounds using a TGF-β like protein. See page 5, lines 9-19. Cerletti et al. teach TGF-β like proteins refers to TGF-β_1, TGF-β_2 and TGF-β_3. See page 4, lines 54-56. Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. In re Best, 195 U.S.P.Q. 430, 433 (CCPA 1977). The composition of Cerletti et al. is the same as that claimed. Thus, the Cerletti et al. composition inherently has the same properties as the composition claimed. The burden of proof is on applicant where rejection is based on inherency under 35 U.S.C. 102. Best, at 433.

Applicant makes similar arguments to those made in the above rejection. They are not persuasive. Applicant references TGF-β_3 and states that Cerlitti does not teach the non-fibrotic character of TGF-β_3. However, Cerletti et al. teach a composition comprising TGF-β_3 for use in would healing. Therefore the Cerletti et al. composition of TGF-β_3 inherently has the same properties as the instant claimed invention. Applicant is again referred to Best. Intended use limitations are not given weight with respect to composition/compound claims. See MPEP 2111.02.

25. No claim allowed. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application may be subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, if this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on

the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192.

THIS APPLICATION IS SUBJECT TO PUBLIC LAW 103-465. Therefore, upon the timely filing of a first submission and the appropriate fee of $750 for a large or ½ that amount for a small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

26. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 308-4242

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. The examiner can normally be reached Monday through Thursday from 6:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

C Eisenschenk

April 8, 1997
Christopher Eisenschenk, Ph.D.
Primary Examiner
Group 1800